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Attached hereto as **Exhibit A** is a marked-up version of the changes made to the claims by the present amendment. Exhibit A is entitled "EXHIBIT A - CLAIMS WITH MARKINGS TO SHOW CHANGES".

Attached hereto as **Exhibit B** is a clean set of all pending claims following entry of this amendment. Exhibit B is entitled "EXHIBIT B - CLEAN SET OF ALL PENDING CLAIMS FOLLOWING ENTRY OF THE PRESENT AMENDMENT". All of the currently pending claims are consolidated in this list for the convenience of the Examiner.

No new subject matter has been added.

#### REMARKS

Claims 38, 39, 41-43, 45, 47, 50, 55-58, 61, 66-69, 73, and 78-81, as amended herein, and Claims 40, 44, 46, 48, 49, 51-54, 59, 60, 62-65, 70-72, 74-77, and 82, as filed with Applicants' Preliminary Amendment dated June 14, 2000, remain in the application.

Applicants have amended Claim 38 by replacing the definite article "the" after the word "from" and before the word "patient's" with the indefinite article "a". Applicants have also amended Claim 38 by inserting the phrase "of the patient" after the word "membrane" and before the word "into".

Applicants have amended Claims 39, 47, 50, 58, 61, 69, 73 and 81 by replacing the word "up" with the phrase "about 0.5%".

Applicants have amended Claim 41 by replacing the term "acetylated amino sugars" with the term "at least one acetylated amino sugar". Applicants have also amended Claim 41 by replacing the term "deacetylated amino sugar" with the term "at least one deacetylated amino sugar".

Applicants have amended Claim 42 by inserting the phrase "at least one" before the term "acetylated amino sugar" and before the term "deacetylated amino sugar".

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Applicants have amended Claim 43 by inserting the term "at least one" before the term "acetylated amino sugar".

Applicants have amended Claims 45, 56, 67 and 79 by deleting the term "bicarbonate".

Applicants have amended Claims 55, 57, 66, 68, 78 and 80 by replacing the phrase "further comprising" with the phrase "wherein said peritoneal dialysis solution further comprises".

Claims 38, 39, 41-43, 45, 47, 50, 55-58, 61, 66-69, 73 and 78-81, as amended herein, have been amended to further define and clarify Applicants' invention and not in accordance with any statutory requirement.

No new subject matter has been added.

#### **Appointment of Associate Agent**

Applicants enclose herewith an appointment of associate agent appointing Kitt Sinden, Registration No. 50,188, as an associate agent for Applicants.

#### **Specification Objections**

The Examiner has objected to the specification under 37 CFR 1.53 for purportedly introducing new matter into the disclosure. The Examiner states that the added material, which is purportedly not supported by the original disclosure, is the inclusion of bicarbonate in Claims 45, 56, 67, 79 and claims that depend from these claims. Without acceding to the Examiner's objection to the specification under 37 CFR 1.53, Applicants have deleted the term "bicarbonate" from Claims 45, 56, 67 and 79. Therefore, the Examiner's objection to the specification under 37 CFR 1.53 is now deemed moot.

#### **Claim Rejections – 35 USC Section 112**

The Examiner has rejected Claims 45-48, 56-59, 67-70 and 79-82 under 35 USC §112, first paragraph, for purportedly containing subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Without acceding to the Examiner's rejection of Claims 45-48, 56-59, 67-70 and 79-82 under 35 USC §112, first paragraph, Applicants have deleted the term "bicarbonate" from Claims 45, 56, 67 and 79. Therefore, the Examiner's rejection of Claims 45-48, 56-59, 67-70 and 79-82, under 35 USC §112, first paragraph, is now deemed moot.

The Examiner has rejected Claim 38 under 35 USC §112, second paragraph, as being indefinite for purportedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner purports that Claim 38 lacks sufficient antecedent bases for the limitation "the" in the third line of the claim. Without acceding to the Examiner's rejection of Claim 38 under 35 USC §112, second paragraph, Applicants have amended Claim 38 by replacing the definite article "the" with the indefinite article "a" and have inserted the phrase "of the patient" after the word "membrane" and before the word "into" in the third line of Claim 38. Applicants submit that there is sufficient antecedent bases in Claim 38, and thus, Applicants respectfully request reconsideration of the Examiner's rejection of Claim 38 under 35 USC §112, second paragraph.

### **Double Patenting**

The Examiner has rejected Claims 38-82 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7 of Wu et al. (US 6,083,935).

Without acceding to the Examiner's rejection of Claims 38-82 based on the non-statutory double patenting ground, Applicants hereby submit a Terminal Disclaimer in compliance with 37 CFR 1.321 (c). Applicants submit that US 6,083,935 to Wu et al. is commonly owned with the present application. Applicants hereby authorize the Examiner to withdraw the amount of U.S. \$55.00 from Deposit Account 08-3255 to cover the fee for filing a Terminal Disclaimer for a small entity. If there is any deficiency or surplusage of the fees required for the Terminal

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Disclaimer, please obtain any such deficiency from or credit the surplusage to Deposit Account 08-3255 and advise Applicants' Agent. In view thereof, Applicants respectfully request reconsideration of the Examiner's rejection of Claims 38-82 under the judicially created doctrine of obviousness-type double patenting.

### **Claim Rejections – 35 USC Section 103**

The present application names joint inventors. Applicants submit that the subject matter of the various claims in the present application was commonly owned at the time any inventions covered therein were made.

The Examiner has rejected Claims 38-44, 49-55, 60-66, and 71-78 under 35 USC 103(a) as being unpatentable over Seyffart et al. (US 4,879,280), and Breborowicz et al. (EP 0 555 087 A1) in view of "Textbook of Biochemistry".

Applicants respectfully submit that they disagree with the Examiner's conclusion. Applicants submit that none of Seyffart et al., Breborowicz et al., the "Textbook of Biochemistry" alone, or any combination thereof, render the claimed invention obvious. Applicants respectfully submit that the Examiner has not established the prima facie case of obviousness. Applicants will show that the Examiner has not demonstrated all elements of the prima facie case, and therefore, in Applicants' respectful submission, the Examiner's opinion of obviousness is deficient and Applicants are deserving of a patent. The Federal Circuit has endorsed this view in *In re Oetiker* (977 F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992)), stating that "if the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." (*Id.*, 24 USPQ 2d at 1444).

Combined decisions from the Federal Circuit and CCPA indicate that a prima facie case of obviousness is established when the Examiner provides:

1. one or more references
2. that were available to the inventor and

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3. that teach
4. a suggestion to combine or modify the references,
5. the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art.

Accordingly, an Applicant who is able to prove that the Examiner has failed to establish any one of these elements will prevent the prima facie case of obviousness from being established.

Applicants herein provide the following in respect of the Examiner's purported prima facie case of obviousness:

### **Element 3: References That Teach**

The third element of the prima facie case of obviousness requires that the references generally place the needed subject matter supporting the obviousness rejection in the public domain before the date of invention (i.e., generally before the filing date of the application) (*In re Zenitz*, 333 F.2d 924, 142 USPQ 158, 160 (C.C.P.A. 1964)). In this regard, the Federal Circuit has stated that "[t]he test for obviousness is not whether the features of one reference may be bodily incorporated into another reference .... Rather, we look to see whether combined *teachings* render the claimed subject matter obvious." (*In re Wood*, 599 F.2d 1032, 202 USPQ 171, 174 (C.C.P.A. 1979) (emphasis added) (citing *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549-50 (C.C.P.A. 1969); *In re Mapelsden*, 329 F.2d 321, 322, 141 USPQ 30, 32 (C.C.P.A. 1964)).)

### **Applicants' Invention**

Applicants' application discloses and claims the following:

38. A peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution.

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Amino sugars are known to persons skilled in the art to be hexose derivatives wherein an amino group (-NH<sub>2</sub>) replaces one of the hydroxyl groups (-OH) in the parent hexose. Some examples of amino sugars include glucosamine, galactosamine, mannosamine, muramic acid, N-acetylglucosamine, N-acetylgalactosamine, N-acetylmannosamine, N-acetylmuramic acid, etc. In the acetylated amino sugars (i.e., N-acetylglucosamine, N-acetylgalactosamine, N-acetylmannosamine, N-acetylmuramic acid), the amino group is condensed with acetic acid.

The at least one amino sugar of the peritoneal dialysis solutions of the present application are present as a monomer or as an oligomer of 2 to 12 carbohydrate units of the same repeating monosaccharide unit joined together (i.e., in one embodiment, 2 to 12 N-acetylglucosamine units joined together) (see page 6, lines 17 to 27, of the present application).

**Teachings of European Patent Application No. 0 555 087 A1 to Breborowicz et al.**

Applicants submit that Breborowicz et al. teach conventional peritoneal dialysis solutions which have been modified to include one or more additives, used alone or in combination, to minimize the injury and physiological effects that peritonitis can cause. One such additive is compounds consisting of the degradation products of hyaluronic acid to enhance the regeneration of the peritoneal mesothelium without fibrosis (see column 6, lines 3 to 41, of EP 0 555 087 A1). The degradation products of hyaluronic acid in the Breborowicz et al. peritoneal dialysis solutions are oligosaccharides (see column 10, lines 3 and 5, of EP 0 555 087 A1). Oligosaccharides are known to persons skilled in the art to consist of short chains of monosaccharide units (i.e., for example, 2 to 8 units in length) joined together by characteristic glycosidic linkages. The most abundant oligosaccharides are the disaccharides, with two monosaccharide units. Hyaluronic acid is known to persons skilled in the art to be a glycosaminoglycan containing alternating units of D-glucuronic acid and N-acetylglucosamine. D-glucuronic acid is known to persons skilled in the art to be an acidic sugar wherein the C-6 of glucose is oxidized to a carboxylate group. Therefore, the degradation products of hyaluronic acid taught by Breborowicz et al. are oligosaccharides, that is, short chains of two different

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alternating monosaccharide units, namely N-acetylglucosamine and glucuronic acid, joined together by glycosidic linkages.

#### **Differences between the Present Application and Breborowicz et al.**

As discussed above, the degradation products of hyaluronic acid present in the peritoneal dialysis solutions of Breborowicz et al. are oligosaccharides, that is, short chains of two different alternating monosaccharide units, namely N-acetylglucosamine and glucuronic acid, joined together by glycosidic linkages. Breborowicz et al. do not teach the use of monomers at all. Breborowicz et al. only teach the use of oligomers (i.e., oligosaccharides). Further, Breborowicz et al. do not teach the use of amino sugars in peritoneal dialysis solutions at all. A degradation product of hyaluronic acid which is an oligosaccharide of 2 units in length consisting of N-acetylglucosamine and D-glucuronic acid as taught by Breborowicz et al. would not be considered to be an amino sugar by a person skilled in the art. Therefore, Breborowicz et al. do not teach the use of at least one amino sugar in a peritoneal dialysis solution at all, let alone the use of at least one amino sugar in a peritoneal dialysis solution wherein the at least one amino sugar is present as a monomer or as oligomers of 2 to 12 carbohydrate units of the same repeating monosaccharide unit as disclosed and claimed in Applicants' application (see page 6, lines 17 to 27, of the present application).

Therefore, Breborowicz et al. did not appreciate Applicants' use of at least one amino sugar in a peritoneal dialysis solution to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution. In Applicants' respectful submission, the Claims of the present invention are not obvious in light of Breborowicz et al. This reference does not teach the subject matter of Applicants' claims (compositions and methods claimed). The teachings of Breborowicz et al. lack a peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution, which Applicants are claiming in the present application.

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In light of the above, Breborowicz et al. has, in Applicants' respectful submission, been addressed as not teaching the present invention and thus the combination of Breborowicz et al. with any or all of Seyffart et al. and the "Textbook of Biochemistry" is not possible since there lacks not only teaching of the invention but motivation to combine the references is also lacking.

**Teachings of United States Patent No. 4,879,280 to Seyffart et al.**

Applicants submit that Seyffart et al. teach a dialysis solution for use in intra-peritoneal dialysis in the form of an aqueous solution having an osmotically active substance in the form of a saccharide characterized in that the saccharide is made up of at least two monosaccharide anhydrides. The saccharides that may be used in the dialysis solutions with at least two monosaccharide anhydrides disclosed by Seyffart et al are, for example, the disaccharides, the trisaccharides, further oligosaccharides and polysaccharides, having a molecular weight less than or equal to 400,000. Examples of the disaccharides are lactose, saccharose, maltose, trehalose, cellobiose, gentiobiose, melibiose, and rutinose. An example of an oligosaccharide, made up of three monosaccharide anhydrides is raffinose. Natural polysaccharides and artificial polysaccharides such as the dextrans are also contemplated for use in the dialysis solutions of Seyffart et al.

**Differences between the Present Application and Seyffart et al.**

As discussed above, the saccharides present in the peritoneal dialysis solutions disclosed in Seyffart et al. are made up of at least two monosaccharide anhydrides. Seyffart et al. do not teach the use of amino sugars in peritoneal dialysis solutions at all, let alone the use of at least one amino sugar in a peritoneal dialysis solution as disclosed and claimed in Applicants' application.

Neither Breborowicz et al. nor Seyffart et al. teach the peritoneal dialysis solutions claimed. Nor would the claimed subject matter be obvious if one adds the "Textbook of Biochemistry". In considering the teachings of the "Textbook of Biochemistry" reference upon which the Examiner relies, it is readily apparent that it might best be described as a general textbook which catalogues a list of various components which make up connective tissue. Such teaching is not related to any



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peritoneal dialysis solution compositions at all, let alone any peritoneal dialysis solution compositions which are in any way analogous to those of the present invention. It is important to keep in mind that the teachings of such a reference must be viewed in connection with the teachings of Seyffart et al. and/or Breborowicz et al. in the absence of the teachings of the present application.

Therefore, it is not seen how one skilled in the art, without the benefit of the teachings of the present application, would be led to arrive at the presently claimed invention.

For the foregoing reasons, the Applicants respectfully submit that the "Textbook of Biochemistry" reference in combination with Breborowicz et al. alone, Seyffart et al. alone, or any combination of Breborowicz et al. with Seyffart et al. would not suggest to a person skilled in the art the instantly claimed solutions.

Applicants have now shown that Breborowicz et al. alone and Seyffart et al. alone are irrelevant and that the "Textbook of Biochemistry" does not add to the Breborowicz et al. and/or Seyffart et al. teachings.

Applicants thus respectfully submit that the presently claimed invention may not properly be said to be prima facie obviousness to one of ordinary skill in the art within the meaning of 35 U.S.C. §103 from the teachings of the cited references.

Applicants respectfully request reconsideration of the Examiner's rejection of Claims 38-44, 49-55, 60-66 and 71-78 under 35 U.S.C. §103(a) as being unpatentable over Seyffart et al. (US 4,879,280) and Breborowicz et al. (EP 0 555 087 A1) in view of the "Textbook of Biochemistry".

The Examiner has also rejected Claims 45-48, 56-59, 67-70 and 79-82 under 35 USC § 103(a) as being unpatentable over Kubo et al. (JP 11-71273-A). Without acceding to the Examiner's rejection of Claims 45-48, 56-59, 67-70 and 79-82 under 35 USC § 103(a), in view of Kubo et al. (JP 11-71273-A), Applicants have amended Claims 45, 56, 67 and 79 by deleting the term "bicarbonate". Therefore, the

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Examiners' rejection of Claims 45-48, 56-59, 67-70 and 79-82 under 35 USC § 103(a) as being unpatentable over Kubo et al. (JP 11-71273-A) is now deemed moot.

Thus, in view of the above, Applicants believe that they have addressed all the issues raised by the Examiner in the Official Action dated January 15, 2002. In so doing, Applicants believe that they have overcome all of the objections and rejections of the Examiner and that the present application is in condition for allowance.

Applicants respectfully request that, should the Examiner have any questions or comments with respect to the response, he should contact Applicants' Representative, Kitt Sinden, collect, at (905) 771-6414 at his convenience prior to issuing a further Office Action or a Notice of Allowance.

Respectfully submitted,

IVOR M. HUGHES



Kitt Sinden

Registration No. 50,188

WKS/jf

Enclosures

1. Requisition for Three-Month Extension of Time
2. Terminal Disclaimer
3. Exhibit A - Claims with Markings to Show Changes
4. Exhibit B - Clean Set of All Pending Claims following Entry of the Present Amendment
5. Appointment of Associate Agent

Application Serial No. 09/593,691  
Group Art Unit 1617

EXHIBIT A

CLAIMS WITH MARKINGS TO SHOW CHANGES

38. (Amended) A peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from [the] a patient's blood across the peritoneal membrane of the patient into the solution.

39. (Amended) The solution of claim 38 wherein the at least one amino sugar is present at a concentration of [up] about 0.5% to about 5.0% (w/v).

41. (Amended) The solution of claim 40 wherein the at least one amino sugar is selected from the group consisting of at least one acetylated amino [sugars] sugar, at least one deacetylated amino [sugars] sugar and combinations thereof.

42. (Amended) The solution of claim 41 wherein the at least one acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmannosamine and combinations thereof and the at least one deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

43. (Amended) The solution of claim 42 wherein the at least one acetylated amino sugar is N-acetylglucosamine.

45. (Amended) The solution of claim 44 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, [bicarbonate] and combinations thereof.

47. (Amended) The solution of claim 46 wherein the at least one amino sugar together with the at least one additional agent is present at a concentration of [up] about 0.5% to about 5.0% (w/v).

50. (Amended) The method of claim 49 wherein the at least one amino sugar is present at a concentration of [up] about 0.5% to about 5.0% (w/v).
55. (Amended) The method of claim 54 wherein said peritoneal dialysis solution further [comprising] comprises at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.
56. (Amended) The method of claim 55 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, [bicarbonate] and combinations thereof.
57. (Amended) The method of claim 56 wherein the peritoneal dialysis solution further [comprising] comprises at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.
58. (Amended) The method of claim 57 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of [up] about 0.5% to about 5.0% (w/v).
61. (Amended) The method of claim 60 wherein the at least one amino sugar is present at a concentration of [up] about 0.5% to about 5.0% (w/v).
66. (Amended) The method of claim 65 wherein said peritoneal dialysis solution further [comprising] comprises at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.
67. (Amended) The method of claim 66 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, [bicarbonate] and combinations thereof.
68. (Amended) The method of claim 67 wherein said peritoneal dialysis solution further [comprising] comprises at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

69. (Amended) The method of claim 68 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of [up] about 0.5% to about 5.0% (w/v).

73. (Amended) The method of claim 72 wherein the at least one amino sugar is present at a concentration of [up] about 0.5% to about 5.0% (w/v).

78. (Amended) The method of claim 77 wherein said peritoneal dialysis solution further [comprising] comprises at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

79. (Amended) The method of claim 78 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, [bicarbonate] and combinations thereof.

80. (Amended) The method of claim 79 wherein said peritoneal dialysis solution further [comprising] comprises at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

81. (Amended) The method of claim 80 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of [up] about 0.5% to about 5.0% (w/v).

Application Serial No. 09/593,691  
Group Art Unit 1617

**EXHIBIT B**

**CLEAN SET OF ALL PENDING CLAIMS FOLLOWING  
ENTRY OF THE PRESENT AMENDMENT**

B<sup>1</sup>  
38. A peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution.

39. The solution of claim 38 wherein the at least one amino sugar is present at a concentration of about 0.5% to about 5.0% (w/v).

40. The solution of claim 39 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

41. The solution of claim 40 wherein the at least one amino sugar is selected from the group consisting of at least one acetylated amino sugar, at least one deacetylated amino sugar and combinations thereof.

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42. The solution of claim 41 wherein the at least one acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmannosamine and combinations thereof and the at least one deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

43. The solution of claim 42 wherein the at least one acetylated amino sugar is N-acetylglucosamine.

44. The solution of claim 43 further comprising at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

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45. The solution of claim 44 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, and combinations thereof.

46. The solution of claim 45 further comprising at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

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47. The solution of claim 46 wherein the at least one amino sugar together with the at least one additional agent is present at a concentration of about 0.5% to about 5.0% (w/v).

*Sub C*

48. The solution of claim 47 wherein

- (a) the pH is in the range of about 5.0 to about 7.4;
- (b) the osmolarity is greater than 280 mOsm/L;
- (c) sodium is present at a concentration in the range of about 115 to about 140 mEq/L;
- (d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEq/L;
- (e) chloride is present at a concentration in the range of about 100 to about 145 mEq/L;
- (f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEq/L; and
- (g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEq/L.

49. A method of performing peritoneal dialysis comprising the introduction of a peritoneal dialysis solution into the peritoneal cavity of a patient, wherein said peritoneal dialysis solution comprises at least one amino sugar, in an effective

amount sufficient to create an osmotic pressure to affect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution.

B<sup>5</sup> 50. The method of claim 49 wherein the at least one amino sugar is present at a concentration of about 0.5% to about 5.0% (w/v).

51. The method of claim 50 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

52. The method of claim 51 wherein the at least one amino sugar is selected from the group consisting of acetylated amino sugars, deacetylated amino sugars and combinations thereof.

53. The method of claim 52 wherein the acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmannosamine and combinations thereof and the deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

54. The method of claim 53 wherein the acetylated amino sugar is N-acetylglucosamine.

B<sup>6</sup> 55. The method of claim 54 wherein said peritoneal dialysis solution further comprises at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

56. The method of claim 55 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, and combinations thereof.

57. The method of claim 56 wherein the peritoneal dialysis solution further comprises at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.



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cont.

58. The method of claim 57 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of about 0.5% to about 5.0% (w/v).

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59. The method of claim 58 wherein

- (a) the pH is in the range of about 5.0 to about 7.4;
- (b) the osmolarity is greater than 280 mOsm/L;
- (c) sodium is present at a concentration in the range of about 115 to about 140 mEq/L;
- (d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEq/L;
- (e) chloride is present at a concentration in the range of about 100 to about 145 mEq/L;
- (f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEq/L; and
- (g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEq/L.

60. A method of treating a patient suffering from renal failure comprising the introduction of a peritoneal dialysis solution into the peritoneal cavity of a patient, wherein said peritoneal dialysis solution comprises at least one amino sugar in an effective amount sufficient to create an osmotic pressure to affect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution.

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61. The method of claim 60 wherein the at least one amino sugar is present at a concentration of about 0.5% to about 5.0% (w/v).


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62. The method of claim 61 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

63. The method of claim 62 wherein the at least one amino sugar is selected from the group consisting of acetylated amino sugars, deacetylated amino sugars and combinations thereof.

64. The method of claim 63 wherein the acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmannosamine and combinations thereof and the deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

65. The method of claim 64 wherein the acetylated amino sugar is N-acetylglucosamine.

 66. The method of claim 65 wherein said peritoneal dialysis solution further comprises at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

67. The method of claim 66 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, and combinations thereof.

68. The method of claim 67 wherein said peritoneal dialysis solution further comprises at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

69. The method of claim 68 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of about 0.5% to about 5.0% (w/v).

70. The method of claim 69 wherein

- (a) the pH is in the range of about 5.0 to about 7.4;
- (b) the osmolarity is greater than 280 mOsm/L;
- (c) sodium is present at a concentration in the range of about 115 to about 140 mEq/L;
- (d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEq/L;
- (e) chloride is present at a concentration in the range of about 100 to about 145 mEq/L;
- (f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEq/L; and
- (g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEq/L.

71. A method of reducing at least one complication associated with peritoneal dialysis, said method comprising the introduction of a peritoneal dialysis solution into the peritoneal cavity of a patient, wherein said peritoneal dialysis solution comprises at least one amino sugar, in an effective amount sufficient to create an osmotic pressure to affect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution.

72. The method of claim 71 wherein the at least one complication associated with peritoneal dialysis is selected from the group consisting of:

- (i) morphological and functional deterioration of the peritoneal membrane;
- (ii) peritonitis;
- (iii) adverse metabolic consequences and related cardiovascular disease;
- (iv) protein malnutrition

and combinations thereof.

73. The method of claim 72 wherein the at least one amino sugar is present at a concentration of about 0.5% to about 5.0% (w/v).

74. The method of claim 73 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

75. The method of claim 74 wherein the at least one amino sugar is selected from the group consisting of acetylated amino sugars, deacetylated amino sugars and combinations thereof.

76. The method of claim 75 wherein the acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmannosamine and combinations thereof and the deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

77. The method of claim 76 wherein the acetylated amino sugar is N-acetylglucosamine.

78. The method of claim 77 wherein said peritoneal dialysis solution further comprises at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

79. The method of claim 78 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, and combinations thereof.

80. The method of claim 79 wherein said peritoneal dialysis solution further comprises at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

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cont.

81. The method of claim 80 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of about 0.5% to about 5.0% (w/v).

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82. The method of claim 81 wherein

- (a) the pH is in the range of about 5.0 to about 7.4;
- (b) the osmolarity is greater than 280 mOsm/L;
- (c) sodium is present at a concentration in the range of about 115 to about 140 mEq/L;
- (d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEq/L;
- (e) chloride is present at a concentration in the range of about 100 to about 145 mEq/L;
- (f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEq/L; and
- (g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEq/L.